PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

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PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43*bis*.1)

Date of mailing *(day/month/year)*	25 OCT 2007
Applicant's or agent's file reference 782-P07-039	**FOR FURTHER ACTION** See paragraph 2 below

International application No.	International filing date *(day month year)*	Priority date *(day month year)*
PCT/US 07/61730	07 February 2007 (07.02.2007)	07 February 2006 (07.02.2006)

International Patent Classification (IPC) or both national classification and IPC
IPC(8) - A61B 17/56; A61F 2/28
USPC - 606/72; 623/23.62

Applicant Marctec, LLC

1. This opinion contains indications relating to the following items:

- [X] Box No. I Basis of the opinion
- [ ] Box No. II Priority
- [ ] Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- [ ] Box No. IV Lack of unity of invention
- [X] Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- [ ] Box No. VI Certain documents cited
- [ ] Box No. VII Certain defects in the international application
- [ ] Box No. VIII Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1*bis*(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/US	Date of completion of this opinion	Authorized officer:
Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-3201	19 September 2007 (19.09.2007)	Lee W. Young PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774

Form PCT/ISA/237 (cover sheet) (April 2007)

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Box No. I Basis of this opinion

1. With regard to the **language**, this opinion has been established on the basis of:

   ☒ the international application in the language in which it was filed.

   ☐ a translation of the international application into _____ which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b)).

2. ☐ This opinion has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43*bis*.1(a))

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, this opinion has been established on the basis of:

   a. type of material

      ☐ a sequence listing

      ☐ table(s) related to the sequence listing

   b. format of material

      ☐ on paper

      ☐ in electronic form

   c. time of filing/furnishing

      ☐ contained in the international application as filed

      ☐ filed together with the international application in electronic form

      ☐ furnished subsequently to this Authority for the purposes of search

4. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

5. Additional comments:

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Box No. V **Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

1. Statement

Novelty (N)	Claims	1-9, 15-60	YES
	Claims	10-14	NO
Inventive step (IS)	Claims	NONE	YES
	Claims	1-60	NO
Industrial applicability (IA)	Claims	1-60	YES
	Claims	NONE	NO

2. Citations and explanations:

Claims 10-14 lack novelty under PCT Article 33(2) as being anticipated by US 6,605,090 B1 Trieu, et al. (hereinafter Trieu).

As per claim 10, Trieu discloses a method for stabilizing a fractured bone ([Abstract]), the method comprising: positioning an elongate plate 142 on the exterior surface of the fractured bone 145; forming a passageway extending through the elongate plate and into the bone 148; positioning a fastener in the passageway 158 (Fig. 7); thermally bonding the fastener to the bone while the fastener is positioned in the passageway ([Abstract], col 6, ln 7-22; col 8, ln 60-67).

As per claim 11, Trieu discloses the method of claim 10 and further wherein the elongate plate and fastener (col 13, ln 42-44) include thermoplastic material (col 14, ln 8-16).

As per claim 12, Trieu discloses the method of claim 11 and further wherein ultrasonic energy is used to thermally bond the fastener to the bone ([Abstract], col 6, ln 7-12; col 6, ln 23-27).

As per claim 13, Trieu discloses the method of claim 12 and further wherein thermally bonding the fastener includes thermally bonding the fastener to the elongate plate whereby the fastener resists relative movement between the bone and elongate plate ([Abstract], col 4, ln 45 -51; col 6, ln 7-22).

As per claim 14, Trieu discloses the method of claim 13 and further including contouring a proximal end of the fastener after thermally bonding the fastener (col 2, ln 23-30; col 2, ln 53-55).

Claims 1-9 and 15-20 lack an inventive step under PCT Article 33(3) as being obvious over US 2005/0240190 A1 Gall, et al. (hereinafter Gall) in view of Trieu.

As per claim 1, Gall discloses a method for stabilizing a fractured bone ([Abstract]), the method comprising: positioning an elongate rod in the medullary canal of the fractured bone (para[0033], [0048], [0049]); and forming a passageway through the cortex of the bone, the passageway extending from the exterior surface of the bone to the medullary canal of the bone (para[0038], [0049], Fig. 8). Gall does not explicitly disclose creating a bonding region on the elongate rod, the bonding region generally aligned with the passageway of the cortex; positioning a fastener in the passageway of the cortex and on the bonding region of the elongate rod; and thermally bonding the fastener to the bonding region of the elongate rod while the fastener is positioned in the passageway of the cortex. Although Trieu focuses the invention on a bone plate ([Abstract]), Trieu does suggest and disclose the use of a rod for stabilizing a fractured bone (col 1, ln 14-17), creating a bonding region on the stabilizer (rod), the bonding region generally alinged with the passageway of the cortex (col 6, ln 41-43; col 8, ln 59-67; Fig. 8); positioning a fastener in the passageway of the cortex and on the bonding region of the stabilizer (rod) ([Abstract], col 2, ln 47-55; Fig. 8); and thermally bonding the fastener to the bonding region of the stabilizer (rod) while the fastener is positioned in the passageway of the cortex ([Abstract], col 4, ln 45-51; col 6, ln 7-23; col 9, ln 18-27; Fig. 7). It would have been obvious to a person of ordinary skill in the art to combine Gall with Trieu to derive the method of claim 1 since both relate to implant fixation devices for stabilizing bone fractures.

As per claim 2, Gall and Trieu disclose the method of claim 1 and Trieu further discloses wherein the elongate rod (col 1, ln 14-17) and fastener ([Abstract]) include thermoplastic material (col 14, ln 8-16).

As per claim 3, Gall and Trieu disclose the method of claim 2 and Trieu further discloses wherein ultrasonic energy is used to thermally bond the fastener to the bonding region of the elongate rod (col 1, ln 14-17; col 6, ln 7-12; col 6, ln 23-27).

As per claim 4, Gall and Trieu disclose the method of claim 3 and Trieu further discloses wherein the bonding region includes a roughened surface on the elongate rod (col 1, ln 14-17; col 7, ln 27-33).

As per claim 5, Gall and Trieu disclose the method of claim 3 and Trieu further suggests wherein the bonding region includes an indentation in the elongate rod (col 1, ln 14-17; col 7, ln 23-33).

As per claim 6, Gall and Trieu disclose the method of claim 3 and Gall (Figs. 2C, 8) and Trieu ([Abstract]), in combination, further suggest wherein the bonding region includes a channel being an extension of the passageway.
-Continued on Supplement.

Supplemental Box

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Continuation of:
Box No. V:

As per claim 7, Gall and Trieu disclose the method of claim 3 and Trieu further discloses wherein thermally bonding the fastener includes thermally bonding the fastener to the cortex of the bone whereby the fastener resists movement between the bone and elongate rod ([Abstract], col 4, ln 45-51; col 6, ln 7-22).

As per claim 8, Gall and Trieu disclose the method of claim 1 and Gall further discloses wherein forming a passageway and creating a bonding region includes drilling a hole completely through the bone 820 and elongate rod 810 (Fig. 8), wherein positioning the fastener includes positioning the fastener in the drilled hole 820 (Fig. 8), and wherein one fastener is secured through two separate cortical areas of the bone simultaneously (Fig. 2C). Gall does not explicitly disclose wherein thermally bonding the fastener includes bonding the fastener to the elongate rod and to two cortex areas of the bone. Trieu does suggest and disclose wherein thermally bonding the fastener includes bonding the fastener to the stabilizer (rod) and to the cortical area of the bone ([Abstract], col 1, ln 14-17; col 5, ln 58-60; col 8, ln 60-67; Fig. 8).

As per claim 9, Gall and Trieu disclose the method of claim 1 and Trieu discloses further including contouring a proximal end of the fastener after thermally bonding the fastener (col 2, ln 23-30; col 2, ln 53-55).

As per claim 15, Gall discloses a method for stabilizing a fractured bone ([Abstract]), the method comprising: positioning an elongate rod in the medullary canal of the fractured bone (para[0033], [0048], [0049]). Gall does not explicitly disclose positioning an elongate plate on the exterior surface of the bone such that the cortex of the bone is positioned between the elongate rod and plate; forming a passageway through the elongate plate and the cortex of the bone, the passageway extending from the exterior surface of the elongate plate to the medullary canal of the bone; creating a bonding region on the elongate rod, the bonding region generally aligned with the passageway; positioning a fastener in the passageway and on the bonding region of the elongate rod; and thermally bonding the fastener to the bonding region of the elongate rod while the fastener is positioned in the passageway. Trieu and Gall, in combination, disclose positioning an elongate plate 142 on the exterior surface of the bone 145 (Trieu, Fig. 7) such that the cortex of the bone is positioned between the elongate rod (Gall, Fig. 8) and plate (Trieu, 142 of Fig. 7); and forming a passageway through the elongate plate 142 and the cortex of the bone 141 (Trieu, Fig. 7), the passageway extending from the exterior surface of the elongate plate (Trieu, 143 of Fig. 7) to the medullary canal of the bone (Gall, para[0033]). Trieu discloses creating a bonding region on the elongate rod, the bonding region generally aligned with the passageway (col 1, ln 14-17; col 6, ln 41-43; col 8, ln 59-67; Fig. 8); positioning a fastener in the passageway and on the bonding region of the elongate rod ([Abstract], col 2, ln 47-55; Fig. 8); and thermally bonding the fastener to the bonding region of the elongate rod while the fastener is positioned in the passageway ([Abstract, col 4, ln 45-51; col 6, ln 7-23; col 9, ln 18-27; Fig. 7).

As per claim 16, Gall and Trieu disclose the method of claim 15 and Trieu further suggests wherien the elongate rod, elongate plate, and fastener include thermoplastic material (col 1, ln 14-17; col 14, ln 8-16).

As per claim 17, Gall and Trieu disclose the method of claim 16 and Trieu further discloses wherein the thermoplastic material is PEEK (col 13, ln 66-67 - col 14, ln 1-9).

As per claim 18, Gall and Trieu disclose the method of claim 17 and Trieu further discloses wherein ultrasonic energy is used to thermally bond the fastener to the bonding region of the elongate rod (col 1, ln 14-17; col 6, ln 7-12; col 6, ln 23-27).

As per claim 19, Gall and Trieu disclose the method of claim 18 and Gall and Trieu further disclose, in combination, wherein thermally bonding the fastener includes thermally bonding the fastener to the elongate plate (Trieu, [Abstract]) whereby the fastener resists relative movement of the elongate rod (Gall, para[0049]) and plate (Trieu, [Abstract], col 5, ln 62-67 - col 6, ln 1-6) with the cortex of the bone therebetween (Trieu, Fig. 7), (Gall, Figs. 2C, 8).

As per claim 20, Gall and Trieu disclose the method of claim 19 and Trieu discloses further including contouring a proximal end of the fastener after thermally bonding the fastener (col 2, ln 23-30; col 2, ln 53-55).

Claims 21-22, 24-28, 32-37, 39-41, 46-47 and 51-53 lack an inventive step under PCT Article 33(3) as being obvious over US 5,100,405 A McLaren (hereinafter McLaren) in view of Trieu.

As per claim 21, McLaren discloses an anchor 50 having a longitudinal axis 24, a distal end 22 and a proximal end 58, wherein the distal end 22 (Fig. 5) is configured for insertion into the second tissue (Fig. 6) and the proximal end 58 defines a bore 58 that extends at least partially along the longitudinal axis of the anchor 50/56/58; and a fastener cap 52 having a lid 52 and a post 54, wherein at least a portion of the post is dimensioned to fit within the anchor bore 56, and wherein the fastener cap 52 defines a channel (Fig. 5) extending at least partially through the post 54 and lid 52 (Fig. 5). McLaren does not explicitly disclose a weldable fastener assembly for attachment of a first tissue or implant material to a second tissue comprising: wherein at least one of the anchor or cap can be welded when an energy source is disposed inside the channel of the fastener cap. Trieu does suggest and disclose a weldable fastener assembly (col 6, ln 7-12) for attachment of a first tissue or implant material 142 to a second tissue 141 (Fig. 7) comprising: wherein at least one of the anchor 158 (Fig. 7) or cap can be welded when an energy source is disposed (col 6, ln 7-12) inside the channel of the fastener cap (McLaren, 52 of Fig. 5). It would have been obvious to a person of ordinary skill in the art to derive claim 21 provided McLaren and Trieu since both relate to devices for securing intracorporeal bone implants.

As per claim 22, McLaren and Trieu disclose the fastener of claim 21 and McLaren further discloses wherein the anchor 50 comprises a helical thread 16 disposed on an outer surface of the distal end 22 of the anchor 50, wherein the thread 16 (Fig. 5) is configured for engaging with the second tissue (Fig. 6).

As per claim 24, McLaren and Trieu disclose the fastener of claim 21 and Trieu discloses further wherein the distal end of the anchor 158 is substantially concial (Fig. 7).

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As per claim 25, McLaren and Trieu disclose the fastener of claim 21 and McLaren and Trieu, in combination, disclose wherein the anchor 154 is configured to be disposed within a tissue bore 148 having a first diameter 155 (Trieu, Fig. 7) and the fastener cap lid (Trieu, 152 of Fig. 7), (McLaren, 52 of Fig. 5; 20 of Fig. 7) is larger than the tissue bore (Trieu, 155 of Fig. 7).

As per claim 26, McLaren and Trieu disclose the fastener of claim 21 and McLaren discloses further comprising one or more projections on the fastener cap post (col 4, ln 51-56; 54 of Fig. 5) and one or more corresponding receptiacles in the anchor bore (56/24 of Fig. 5), wherein engagement of the fastener cap post projections 54 with the anchor bore receptacles 56/24 increases the force required to separate the anchor and fastener cap (col 5, ln 51-56; Fig. 5).

As per claim 27, McLaren and Trieu disclose the fastener of claim 21 and Trieu further suggests wherein the anchor is comprised of hydrophilic material ([Abstract]).

As per claim 28, McLaren and Trieu disclose the fastener of claim 21 and McLaren and Trieu further disclose wherein the anchor (Trieu, [Abstract]) and fastener cap (McLaren, col 6, ln 15-21) are substantially free of energy directors.

As per claim 32, McLaren and Trieu disclose the fastener of claim 21 and Trieu further discloses wherein at least one of the anchor and fastener cap is made of PEEK (col 13, ln 66-67 - col 14, ln 1-9).

As per claim 33, McLaren discloses an anchor 50 having a longitudinal axis 24, a distal end 22 and a proximal end 58, wherein the distal end 22 (Fig. 5) is configured for insertion into the second tissue (Fig. 6) and the proximal end 58 defines a bore 24/56/58 that extends at least partially along the longitudinal axis 24 of the anchor 50, and wherein a first helical thread is disposed on the interior surface of the anchor bore 56; and a fastener cap 52 having a lid 52 and a post 54, wherein at least a portion of the post 54 has a second helical thread 54 dimensioned to engage with the first helical thread 56 on the anchor (Fig. 5). McLaren does not explicitly disclose a weldable fastener assembly for attachment of a first tissue or implant material to a second tissue comprising: wherein at least one of the anchor or cap can be welded when an energy source is disposed inside the channel of the fastener cap. Trieu does disclose a weldable fastener assembly (col 6, ln 7-12) for attachment of a first tissue or implant material 142 to a second tissue 141 (Fig. 7) comprising: wherein at least one of the anchor 158 (Fig. 7) or cap can be welded when an energy source is disposed (col 6, ln 7-12) inside the channel of the fastener cap (McLaren, 52 of Fig. 5).

As per claim 34, McLaren and Trieu disclose the fastener of claim 33 and McLaren and Trieu, in combination, further disclose wherein the fastener cap 52 defines a channel extending at least partially through the post 54 and lid 52 (McLaren, Fig. 5) for receiving the energy source (Trieu, col 6, ln 7-12).

As per claim 35, McLaren and Trieu disclose the fastener of claim 35 and McLaren further discloses wherein the anchor 50 comprises a third helical thread 16 disposed on an outer surface of the distal end 22 of the anchor 50, wherein the third thread 16 (Fig. 5) is configured for engaging with the second tissue (Fig. 6).

As per claim 36, McLaren and Trieu disclose the fastener of claim 33 and McLaren further discloses wherein the anchor 50 is substantially cylindrical (Fig. 5).

As per claim 37, McLaren and Trieu disclose the fastener of claim 33 and Trieu further discloses wherein the anchor is comprised of hydrophilic material ([Abstract]).

As per claim 39, McLaren and Trieu disclose the fastener of claim 33 and McLaren suggests an anchor 50 comprising an inner core 24 that could be made of a first material and an outer layer 50 that could be comprised of a second material (col 6, ln 15-21). McLaren does not explicitly disclose a first material that is thermoplastic and weldable. Trieu does disclose a first material that is thermoplastic and weldable (col 13, ln 42-67 - col 14, ln 1-16).

As per claim 40, McLaren and Trieu disclose the fastener of claim 39 and McLaren further suggests wherein the outer layer of the anchor comprises metallic material (col 6, ln 15-21).

As per claim 41, McLaren and Trieu disclose the fastener of claim 39 and McLaren suggests an anchor 50 comprising an inner core 24 that could be made of a first material and an outer layer 50 that could be comprised of a second material (col 6, ln 15-21). Trieu also suggests that the outer layer of the anchor could be made of a second weldable thermoplastic material that could have a higher welding temperature than the material of the inner core, as Trieu discloses that different combinations of various thermoplastic materials could be used to create anchor materials (col 13, ln 42-67 - col 14, ln 1-16).

As per claim 46, McLaren discloses an anchor 50 havnig a longitudinal axis 24, a distal end 22 and a proximal end 58, wherein the distal end 22 (Fig. 5) is configured for insertion into the second tissue (Fig. 6) and the proximal end 58 defines a proximal tip 58/56/50 extending away from the distal end 22 of the anchor 50; and a fastener cap 52 having a lid 52 and a post 54, wherein the distal end of the post 54 defines a receptacle that is configured to receive the proximal tip 58 of the anchor (Fig. 5; 20 of Fig. 7), and wherein the fastener cap 52 further defines a channel extending at least partially through the post 54 and lid 52 (Fig. 5). McLaren does not explicitly disclose a weldable fastener assembly for attachment of a first tissue or implant material to a second tissue comprising: wherein at least one of the anchor or cap can be welded when an energy source is disposed inside the channel of the fastener cap. Trieu does disclose a weldable fastener assembly (col 6, ln 7-12) for attachment of a first tissue or implant 142 material to a second tissue 141 (Fig. 7) comprising: wherein at least one of the anchor 158 (Fig. 7) or cap can be welded when an energy source is disposed (col 6, ln 7-12) inside the channel of the fastner cap (McLaren, 52 of Fig. 5). In combination, McLaren and Trieu disclose all of the elements of claim 46.

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As per claim 47, McLaren and Trieu disclose the fastener of claim 46 and McLaren further discloses wherien the proximal tip extends along the longitudinal axis 24 of the anchor 50 (Fig. 5).

As per claim 51, McLaren and Trieu disclose the fastener of claim 46 and McLaren further discloses wherein the anchor 50 further comprises a helical thread 16 disposed on an outer surface of the distal end 22 of the anchor 50, wherein the thread 16 (Fig. 5) is configured for engaging with the second tissue (Fig. 6).

As per claim 52, McLaren and Trieu disclose the fastener of claim 46 and Trieu further discloses wherein the fastener cap is comprised of hydrophilic material ([Abstract]).

As per claim 53, McLaren and Trieu disclose the fastener of claim 46 and Trieu further discloses wherein at least one of the anchor and fastener cap is made of PEEK (col 13, ln 66-67 - col 14, ln 1-9).

Claim 23 lacks an inventive step under PCT Article 33(3) as being obvious over McLaren and Trieu and further in view of US 2006/0009855 A1 Goble, et al. (hereinafter Goble).

As per claim 23, McLaren and Trieu disclose the fastener of claim 22 and Goble further discloses wherein the helical thread disposed on the outer surface of the distal end of the anchor is a self-tapping thread (para[0116]). It would have been obvious to a person of ordinary skill in the art to derive claim 23 provided McLaren, Trieu and Goble since all relate to devices for securing intracorporeal bone and soft tissue implants.

Claims 54-56 and 58 lack an inventive step under PCT Article 33(3) as being obvious over US 5,660,225 A Saffran (hereinafter Saffran) in view of Trieu.

As per claim 54, Saffran discloses a method for stabilizing fractured bone ([Abstract]), the method comprising: wrapping the sheet of material around a portion of a fractured bone so that at least a first portion of the sheet overlaps with a second portion of the sheet (col 6, ln 62-67 - col 7, ln 1-12). Saffran does not explicitly disclose providing a sheet of weldable, thermoplastic material; exposing the overlapping first and second portions of the sheet disposed around the fractured bone to an energy source; and welding at least a portion of the overlapping first and second portions of the sheet to stabilize the fractured bone. Trieu does suggest and disclose providing a sheet of weldable, thermoplastic material (col 13, ln 42-67 - col 14, ln 1-16); exposing portions of the sheet disposed around a fractured bone to an energy source (col 4, ln 48-51); and welding at least a portion of overlapping portions of the sheet to stabilize the fractured bone (col 6, ln 7-17; Fig. 17). It would have been obvious to a person of ordinary skill in the art to derive claim 54 provided Saffran and Trieu since both relate to devices for securing intracorporeal bone implants and since all elements of claim 54 are disclosed, in combination, by Saffran and Trieu.

As per claim 55, Saffran and Trieu disclose the method of claim 54 and Trieu suggests and discloses further comprising the step of exposing the sheet to the energy source for a sufficient time to cause the sheet to shrink and apply compressive force to the fractured bone (col 4, ln 48-62; col 6, ln 59-67 - col 7, ln 1-10).

As per claim 56, Saffran and Trieu disclose the method of claim 54 and Trieu suggests and discloses wherein the weldable sheet is a mesh material that perimts passage of body fluid (col 8, ln 19-50). Although Trieu focuses on the fastener permitting the passage of body fluid, the bone plate can also be composed of the same material as the disclosed fastener.

As per claim 58, Saffran discloses a method for stabilizing a damaged tissue ([Abstract]), the method comprising: wrapping the sheet of material around a portion of the damaged tissue so that at least a first portion of the sheet overlaps with a second portion of the sheet (col 6, ln 62-67 - col 7, ln 1-12) to form a tube-like structure (Fig. 1). Saffran does not explicitly disclose providing a sheet of weldable, thermoplastic material; exposing the overlapping first and second portions of the sheet disposed around the tissue to an energy source; and welding at least a portion of the overlapping first and second portions of the sheet to stabilize the tissue. Trieu does suggest and disclose providing a sheet of weldable, thermoplastic material (col 13, ln 42-67 - col 14, ln 1-16); exposing portions of the sheet disposed around a the tissue to an energy source (col 4, ln 48-51); and welding at least a portion of overlapping portions of the sheet to stabilize the tissue (col 6, ln 7-17; Fig. 17). It would have been obvious to a person of ordinary skill in the art to derive claim 58 provided Saffran and Trieu since both relate to devices for securing intracorporeal bone/tissue implants and since all elements of claim 58 are disclosed, in combination, by Saffran and Trieu. Also, claim 54 is the same as claim 58, since bone is a type of tissue.

Claim 59 lacks an inventive step under PCT Article 33(3) as being obvious over Saffran and Trieu and further in view of US 2006/0024357 A1 Carpenter, et al. (hereinafter Carpenter).

As per claim 59, Saffran and Trieu disclose the method of claim 58 and Carpenter further discloses wherein the damaged tissue is a blood vessel (para[0208]), and wherein the method further comprises the step of using a balloon in the vessel to increase structural rigidity of the vessel (para[0005]). Carpenter does not explicitly disclose during welding of the sheet of material. Trieu does disclose welding of the sheet of material (col 6, ln 7-12). It would have been obvious to a person of ordinary skill in the art to derive claim 59 provided Saffran, Trieu and Carpenter since all relate to devices for securing intracorporeal bone/soft tissue/blood vessel implants.

Claims 29-31 and 38 lack an inventive step under PCT Article 33(3) as being obvious over McLaren and Trieu and further in view of US 6,174,324 B1 Egan, et al. (hereinafter Egan).

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As per claim 29, McLaren and Trieu disclose the fastener of claim 21 and Egan discloses further comprising a welding instrument having a horn that contacts the fastener and an elongated extension (col 5, ln 23-44; Fig. 3, 110 of Fig. 7). Egan does not explicitly disclose the fastener cap lid and the fastener cap channel. McLaren discloses the fastener cap lid and the fastener cap channel (52 of Fig. 5). It would have been obvious to a person of ordinary skill in the art to derive claim 29 provided Egan, McLaren and Trieu since all relate to devices for securing intracorporeal bone and soft tissue implants and since the disclosed welding horn could be capable of contacting the disclosed fastener cap lid and the fastener cap channel.

As per claim 30, McLaren, Trieu and Egan disclose the fastener of claim 29 and Egan and McLaren, in combination, disclose wherein the elongated extension is configured to expose the energy source (Egan, col 5, ln 23-44; Fig. 3, 110 of Fig. 7) to the fastener cap along the entire length of the channel (McLaren, 52 of Fig. 5).

As per claim 31, McLaren, Trieu and Egan disclose the fastener of claim 29 and Egan and McLaren, in combination, disclose wherein the elongated extension is configured to expose energy (Egan, col 5, ln 23-44) to a distal end 56/58 of the fastener cap post 54 disposed within the anchor bore 24/56/58 (McLaren, Fig. 5).

As per claim 38, McLaren and Trieu disclose the fastener of claim 34 and Egan discloses further comprising a welding instrument having an elongated extension configured to fit within a small intracorporeal implant (col 5, ln 23-44; Fig. 3, 100 of Fig. 7). Egan does not explicitly disclose the fastener cap channel. McLaren does disclose the fastener cap channel (Fig. 5). It would have been obvious to a person of ordinary skill in the art to derive claim 38 provided Egan, McLaren and Trieu since all relate to devices for securing intracorporeal bone and soft tissue implants and since the disclosed welding horn could be capable of contacting the disclosed fastener cap lid and the fastener cap channel.

Claims 42-45 lack an inventive step under PCT Article 33(3) as being obvious over Gall and Trieu and further in view of McLaren.

As per claim 42, Trieu discloses a weldable bone plate assembly ([Abstract]) comprising: a bone plate comprising a thermoplastic, weldable material (col 13, ln 42-67 - col 14, ln 1-16); a fastener 158 to be disposed through the plate 142 (Fig. 7); and wherein at the fastener can be welded to at least one of the intermedullary rod and bone plate when an energy source is applied to the bone plate fastener ([Abstract], col 6, ln 7-12). Trieu does not explicitly disclose an intermedullary rod; or a fastener having a lid and a post, wherein at least a portion of the post is dimensioned to extend into at least a portion of the intermedullary rod, and wherein the fastener lid and post define a channel extending at least partially therethrough. McLaren does disclose a fastener 50 having a lid 52 and a post 54; and wherein the fastener lid 52 and post 54 define a channel extending at least partially therethrough (Fig 5). Gall does further disclose an intermedullary rod (para[0033]); wherein at least a portion of the post 820 is dimensioned to extend into at least a portion of the intermedullary rod 810 (Fig. 8). It would have been obvious to a person of ordinary skill in the art to derive claim 42 provided Gall, Trieu and McLaren since all relate to devices for securing intracorporeal bone and soft tissue implants and since all elements of claim 42 are previously disclosed by these references.

As per claim 43, Gall, Trieu and McLaren, in combination, disclose the assembly of claim 42 and Trieu discloses further wherein the intramedullary rod is comprised of a thermoplastic, weldable material (col 1, ln 14-17; col 13, ln 42-67 - col 14, ln 1-16).

As per claim 44, Gall, Trieu and McLaren, in combination, disclose the assembly of claim 42 and Trieu discloses further wherein the bone plate is comprised of a thermoplastic, weldable material ([Abstract], col 13, ln 42-67 - col 14, ln 1-16).

As per claim 45, Gall, Trieu and McLaren, in combination, disclose the assembly of claim 44 and Trieu discloses a bone plate ([Abstract]). It would have been obvious to a person of ordinary skill in the art to derive claim 45 of a bone plate that is substantially free of pre-formed, threaded holes, since bone plates manufactured with pre-formed, threaded holes are created from bone plates that are substantially free of pre-formed threaded holes. Therefore, it would have been obvious to a person of ordinary skill in the art to derive claim 45 provided Gall, Trieu and McLaren.

Claims 48-50 lack an inventive step under PCT Article 33(3) as being obvious over McLaren and Trieu and further in view of US 6,056,751 A Fenton (hereinafter Fenton).

As per claim 48, McLaren and Trieu, in combination, disclose the fastener of claim 46 and Fenton discloses further wherein an anchor 18 comprises a plurality of proximal tips 24/50 (Fig. 8). It would have been obvious to a person of ordinary skill in the art to derive claim 48 provided McLaren, Trieu and Fenton since all relate to devices for securing intracorporeal bone and/or soft tissue implants and since all elements of claim 48 are previously disclosed by these references.

As per claim 49, McLaren, Trieu and Fenton, in combination, disclose the fastener of claim 48 and Fenton discloses further wherein at least two of the plurality of proximal tips 24/50 are parallel to each other (Fig. 8).

As per claim 50, McLaren, Trieu and Fenton, in combination, disclose the fastener of claim 48 and Fenton obviates wherein the assembly further comprises a plurality of fastener caps corresponding in number to the number of proximal tips. Provided Fenton's disclosure of a plurality of proximal anchor tips and a cap for covering the plurality of anchor tips, it would have been obvious to a person of ordinary skill in the art to create a plurality of fastener caps, instead of only one fastener cap, corresponding to the number of proximal anchor tips.

Claim 60 lacks an inventive step under PCT Article 33(3) as being obvious over Saffran and Trieu and further in view of US 5,487,844 A Fujita (hereinafter Fujita).

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No

PCT/US 07/61730

Supplemental Box

In case **the space in any of the preceding boxes is not sufficient.**

Continuation of:
Box No. V:

As per claim 60, Saffran and Trieu, in combination, disclose the method of claim 58 and Trieu discloses a sheet of weldable, thermoplastic material ([Abstract], col 13, ln 42-67 - col 14, ln 1-16). Trieu does not explicitly disclose comprising at least one impermeable layer. Fujita discloses an impermeable laminated layer sheet that could be combined with Saffran and Trieu (col 6, ln 29-39). It would have been obvious to a person of ordinary skill in the art to derive claim 60 provided Saffran, Trieu and Fujita since Fujita discloses an impermeable laminated layer sheet, which is inherently obvious in many scientific arts and has utility in biomedical applications.

Claim 57 lacks an inventive step under PCT Article 33(3) as being obvious over Saffran and Trieu and further in view of US 2005/0246021 A1 Ringeisen, et al. (hereinafter Ringeisen) and Fujita.

As per claim 57, Saffran and Trieu disclose the method of claim 54 and Ringeisen discloses wherein the sheet comprises two or more layers of laminated materials (para[0088]). Ringeisen does not explicitly disclose a weldable sheet or wherein at least one layer is an impermeable membrane. Fujita discloses wherein at least one layer is an impermeable membrane (col 6, ln 29-39). Trieu discloses a weldable sheet (col 13, ln 42-67 - col 14, ln 1-16). It would have been obvious to a person of ordinary skill in the art to derive claim 57 since Saffran, Trieu and Ringeisen relate to devices for securing intracorporeal bone and/or soft tissue implants. It would have been obvious to a person of ordinary skill in the art to combine Saffran, Trieu and Ringeisen further with Fujita, since Fujita discloses an impermeable laminated layer sheet, which is inherently obvious in many scientific arts and has utility in biomedical applications

Claims 1-60 have industrial applicability as defined by PCT Article 33(4) because the subject matter can be made or used in industry